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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,882	03/01/2002	Syed Z. Salahuddin	015280-212210US	8486

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EXAMINER	
SALIMI, ALI REZA	10

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/087,882	Salahuddin et al
Examiner	**Art Unit**
A. R. SALMI	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 12, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, and 4-12* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, and 4-12* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

This is a response to the amendment B, paper No.8, filed 2/12/2003. Claims 1, 2, 4, and 12 have been amended. Claims 1, 2, 4-12 are pending before the examiner.

Drawings

The corrected or substitute drawings were received on 2/12/03. These drawings have been accepted by the Draftsman.

Please note any grounds of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Reissue Applications

In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed. Please note, each time the claim(s) in a reissue application is/are amended a new Oath/dec is required.

Claims 1, 2, 4-12 are rejected as being based upon a defective Oath under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

> "Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

The amendment filed 2/12/2003 proposes amendments to Claims, 2, 4, and 12 are improper that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

Applicant is also notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

Reissue Applications

Applicants' statement regarding the surrender of the original patent is noted. However, the objection is respectfully maintained until such time wherein the original patent is surrendered to the Office.

Claim Rejections - 35 USC § 112

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced in the previous Office Action mailed 11/6/2002. Applicants argue that claim 1 explicitly recites that the antibodies bind to a herpes virus with genomic DNA that hybridizes to the nucleic acid of molecular clone ATCC Accession No. 40,247, not to all herpes viruses. Applicants' argument as part of amendment B, Paper NO. 8, filed 2/12/2003 has been considered fully, but they are not persuasive. Claim 1 is still vague and indefinite, since the "stringent" is a relative term. The conditions wherein the applicants regard as "stringent' should be specifically recited. What applicants regard as stringent might be considered as non-stringent to others. As stated previously the claim has been interpreted in light of the specification and since the specification does not set forth the intended conditions of "stringent conditions" the claim is vague and indefinite. Applicants do not present any argument for the limitation of the "stringent", and yet the limitation is still present. The rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 1, 2, 4-12 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the previous Office Action mailed 11/6/2002. Applicants argue the present invention is a new HBLV (HHV-6) virus and the invention has opened the door to composition and methods for studying herpes viruses. Applicants argue the claims are directed to antibodies which bind to an antigenic molecule of HHV-6 wherein the genomic DNA from the HHV-6 hybridizes

to the nucleic acid of molecular clone ATCC Accession No. 40,247 and method of detecting such antibodies in a biological sample. Applicants further, assert, the claims do not encompass against all HHV-6 types nor do the claims encompass antibodies against all herpes viruses. The claims, applicants assert, are directed only to antibodies which specifically bind to antigenic molecules of HHV-6 set forth in the claims. Applicants argue that the both claims and the specification require that the HHV-6 antigens to which the antibodies bind be from an HHV-6 virus with genomic DNA that hybridizes to the nucleic acid of molecular clone ZVH14. Applicants argue undue breath is not inappropriate where "one of skill in the art could readily determine any one of the claimed embodiments." Applicants conclude that ample guidance in the specification and claims provide ample guidance in the specification and claims for one of skill in the art to identify the claimed antibodies directed against the particular HHV-6 recited in the claims without undue experimentation. Applicants' argument as part of amendment B, Paper NO. 8, filed 2/12/2003 has been considered fully, but they are not persuasive. At the onset Applicants are reminded that even the pioneering invention has to be enabling absent undue experimentation. In addition, if applicants do not appreciate the broad scope of their own invention the Office certainly does. Applicants would like to dismiss the broad scope of the claimed invention as routine in the art, but such is not the case. There is nothing in the specification that teaches about the conditions that would lends itself in identifying all pieces of DNA that may or may not be part of a HHV-6. Applicants have not provided any evidence which would show one of skill in the art would readily identify a DNA as part of HHV-6 fragment absent undue experimentation, and such assertion is

seen as an unsupported assertion. Still further, it appears Applicants understanding of the scope of their claimed invention is misplaced. The claims are not directed to raising antibodies against the deposited virus. The Office views raising the antibodies against the deposited virus as routine, even though, applicants provide no evidence they ever raised antibodies against the virus. However, since, applicants isolated the virus, it is concluded that raising the antibodies against the viral antigen of the virus identified as ATCC Accession No. 40,247 would be within the purview of one of skill in the art. Having said that what was argued by the Office in previous action was mostly directed to all the other antibodies that are suppose to be generated to the viruses that have not been taught, and yet have been claimed. Applicants are the ones requesting patent protection and the disclosure should provide adequate teaching for one of ordinary skill in the art to enable the claimed invention absent undue experimentation. Applicants cannot rely on others to enable their claimed invention. The scope of Applicants' claimed invention is not directed to raising antibodies against known antigens. One of skill in the art is first suppose to identify a pieces of a DNA or RNA that hybridizes under all types of conditions to the DNA of the deposited virus. Then the skilled artisan is suppose to clone the piece the DNA or RNA which is considered to perhaps be a part of HHV-6 and express the protein and then raise antibody to the expressed protein. These are not routine experimentations, since the specification does not provide the conditions for the hybridizations. Huge number of false positive clones and/or antibodies would result. As stated previously no hybridization conditions is taught for the one ordinary skill in the art to determine which sequences would be encompassed within the scope of

the claimed invention. Absent clear teaching undue experimentation would be required to enable the full scope of the claims. In addition, applicants repeated assertion to the morphology limitation is noted, however, the hybridization is not one- to-one ratio. Applicants are requesting patent protection for all serotypes of HHV-6 and their antibodies. Albeit, they only isolated one HHV- 6 and never isolated any antibodies. To isolate all other HHV-6 types that may or may not hybridize to the deposited virus absent any teaching by the applicants would be undue experimentation. No condition is given and the arbitrarily condition of hybridization would mean a whole host of false positive DNAs, their proteins and subsequently their antibodies which should be screened, this is not routine especially given the date of filing. Moreover, the antibody recognition of an epitope on an antigenic polypeptide and its level of binding specificity has no bearing on "stringent" hybridization assay. Antibody specificity mostly concerns itself with polypeptide folding and availability of antigenic regions. In other words, whether a piece of DNA can hybridize to another piece of DNA does not provide teaching for characterization of the antibodies and how one of skill in the art would know what is and isn't encompassed. To characterize the antibodies absent any teaching by the disclosure one of ordinary skill in the art would be required to conduct large quantity of experimentations, and still would not know what antibodies are ascertained within the scope of claimed invention. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the

intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988)*. The rejection is respectfully maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-12 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the previous Office Action mailed 11/6/2002. Applicants argue that all of the claims as presently pending are adequately described in the specification. Applicants add as set forth in the MPEP § 2163 IIA3 (a), adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person would recognize the inventor had possession of the claimed invention. In addition, applicants refer the examiner to Example 16 of the Written description Guidelines training Materials, where it's stated that written description is satisfied for the claimed antibody if the specification teaches that an antigen has been isolated and its useful for detection of viral infection. Applicants' argument as part of amendment B, Paper NO. 8, filed 2/12/2003 has been considered fully, but they are not persuasive. Applicants do not argue that they were not in possession of all the antibodies or the DNA molecules that can be translated into protein from which antibodies can then be formed. They are arguing that they should be entitled to all the antibodies and all the DNA molecules that

bind to the deposited virus at all conditions, because they were in possession of one virus. Once again applicants underestimate the scope and written description of their claimed invention. Applicants are reminded that not only they are asking for all viruses that fall within the limitation of recited morphology in the claims, but also all of the small pieces of DNA that hybridize to the deposited virus which applicants may call as part of a greater virus, and the scope of the claims cover any antibody that is raised against the protein of said small DNA. In other words, the hybridization is not one- to-one ratio, one doesn't have to isolate a double stranded DNA virus of 170 Kb and find out whether or not hybridizes to the applicants' deposit virus. Any piece of DNA, where no structure has been given, which happens to hybridize under any condition falls within the claimed invention. Applicants were not in possession of any and all pieces of nucleic acid at the time of filing which can hybridize under all conditions to the deposited virus. In other words if one skilled in the art comes across a small piece of DNA which she/he raises antibody against, that very antibody is covered under applicants' claims, even though applicants provide to teaching for the structure of the small DNA, and they never possessed either the DNA nor the antibody. Still further, applicants are stating they were in possession of all HHV-6 serotypes at the time of filing because of hybridization limitation. But the structure of all serotypes that may vary from the deposited virus were not disclosed, and applicants were not in possession of all serotypes and they never disclosed their structure.

In addition, the Example 16 of the Written description Guidelines training Materials is actually what Office has argued and strengthens Office's position rather than the applicants position.

Antigen X in the Example 16 is similar to the Deposited virus of the applicants, and the Office has indicated that raising antibodies against the virus is routine and the written description is satisfied for the antibodies against the deposited virus, albeit, the applicants were not in possession of any antibody against the deposited virus. The Example 16 of the Written description Guidelines training Materials does not say the Written description is satisfied for all other virus types which applicants have not taught, disclosed, or possessed (emphasis added). Applicants are not asking for patent protection for the antibodies against the deposited virus, but all antibodies against all pieces of DNA of all sizes, small or large, and serotypes of the HHV-6 that may hybridize under any and all conditions to their deposited virus. However, since the structure of the various serotypes have not been taught, and applicants were not in possession of the serotypes or their fragments thereof the written description is lacking. The rejection is maintained.

NEW GROUNDS OF REJECTION:

Claim Rejections - 35 USC § 112

Claims 4-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is vague and indefinite, for recitation of the "stringent" which is a relative term. The conditions wherein the applicants regard as "stringent' should be specifically recited. What applicants regard as stringent might be considered as non-stringent to others. The claim has been interpreted in light of the specification and since the specification does not set forth the intended conditions of "stringent conditions" nor the metes and bounds of the intended antibodies the claim is vague and indefinite. This affects the dependent claims.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

3/5/2003

ALI R. SALIMI
PRIMARY EXAMINER